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PATENT

Docket No.: 19226/2081 (R-5661)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Balasubramanian et al.

Serial No. : 10/000,226

Cnfrm. No. : 9220

Filed : November 30, 2001

For : METHOD OF COMPLEXING A PROTEIN  
BY THE USE OF A DISPERSED SYSTEM  
AND PROTEINS THEREOFExaminer:  
UnknownArt Unit:  
1645

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SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR §§ 1.97-1.98U.S. Patent and Trademark Office  
Box 2327  
Arlington, Virginia 22202  
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Dear Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, applicants hereby bring to the attention of the United States Patent and Trademark Office, pursuant to 37 C.F.R. §§ 1.97-1.98, the enclosed documents listed on the attached PTO-1449 form.

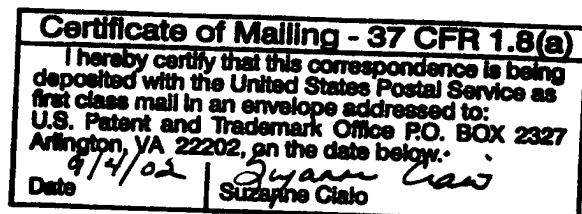
A copy of the International Search Report for the counterpart PCT application issued not more than three months prior to the filing of this Statement is enclosed.

Pursuant to 37 C.F.R. § 1.97(b), no fee is required. If additional fees are required, however, the Commissioner is hereby authorized to charge any fees to Deposit Account No. 14-1138.

It is respectfully requested that an Examiner-initialed copy of this form be returned to the undersigned.

Respectfully submitted,

Date: 9/4/02

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U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE  SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT  (use several sheets if necessary)  (PTO-1449)	ATTY. DOCKET NO.	SERIAL NO.
	19226/2081 (R-5661)	10/000,226
	APPLICANT	
	Balasubramanian et al.	
	FILING DATE	GROUP ART UNIT
	November 30, 2001	1645

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPRO- PRIATE
	1	5,013,556	05/07/1991	Woodle et al.			
	2	5,952,198	09/14/1999	Chan			

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANS- LATION IF APPRO- PRIATE
	3	WO 99/55306	11/04/1999	WIPO			

## OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)

	1	Larner, "The Molecular Pathology of Haemophilia," <u>Quarterly J. Med.</u> , 63(242):473-491 (1987)
	2	Toole et al., "Molecular Cloning of a cDNA Encoding Human Antihaemophilic Factor," <u>Nature</u> , 312:342-347 (1984)
	3	Wood et al., "Expression of Active Human Factor VIII From Recombinant DNA Clones," <u>Nature</u> , 312:330-336 (1984)
	4	Fay, "Factor VIII Structure and Function," <u>Thrombosis and Haemostasis</u> , 70(1):63-67 (1993)
	5	Foster et al., "Factor VIII Structure and Function," <u>Blood Reviews</u> , 3:180-191 (1989)
	6	Yoshimoto et al., "Oxidative Refolding of Denatured/Reduced Lysozyme Utilizing the Chaperone-Like Function of Liposomes and Immobilized Liposome Chromatography," <u>Biotechnol. Prog.</u> , 15:480-487 (1999)
	7	Kanaoka et al., "Stabilization of Aerosolized IFN- $\gamma$ by Liposomes," <u>Int. J. Pharmaceutics</u> , 188:165-172 (1999)
	8	Woodle, "Surface-Modified Liposomes: Assessment and Characterization for Increased Stability and Prolonged Blood Circulation," <u>Chem. Phys. Lipids</u> , 64:249-262 (1993)
EXAMINER		DATE CONSIDERED
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.		

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	APPLICANT Balasubramanian et al.	SEP 09 2002 PATENT & TRADEMARK		
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## FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRAN- SLATION IF APPRO- PRIATE

## OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)

9	Gilbert et al., "Specific Membrane Binding of Factor VIII is Mediated by O-Phospho-L-Serine, A Moiety of Phosphatidylserine," <u>Biochem.</u> , 32:9577-9587 (1993)
10	Gilbert et al., "Binding of Human Factor VIII to Phospholipid Vesicles," <u>J. Biol. Chem.</u> , 265(2):815-822 (1990)
11	Hilbich et al., "Aggregation and Secondary Structure of Synthetic Amyloid $\beta$ A4 Peptides of Alzheimer's Disease," <u>J. Mol. Biol.</u> , 218:149-163 (1991)
12	Hammarström et al., "Structural Mapping of an Aggregation Nucleation Site in a Molten Globule Intermediate," <u>J. Biol. Chem.</u> , 274(46):32897-32903 (1999)
13	Tsai et al., "Formulation Design of Acidic Fibroblast Growth Factor," <u>Pharmaceutical Res.</u> , 10(5):649-659 (1993)
14	Carpenter et al., "Rational Design of Stable Lyophilized Protein Formulations: Some Practical Advice," <u>Pharmaceutical Res.</u> , 14(8):969-975 (1997)
15	Foster et al., "Synthetic Factor VIII Peptides With Amino Acid Sequences Contained Within the C2 Domain of Factor VIII Inhibit Factor VIII Binding to Phosphatidylserine," <u>Blood</u> , 75(10):1999-2004 (1990)
16	Kalafatis et al., "Factor Va-Membrane Interaction is Mediated by Two Regions Located on the Light Chain of the Cofactor," <u>Biochem.</u> , 33:486-493 (1994)
17	Lecompte, et al. "Electrostatic and Hydrophobic Interactions Are Involved in Factor Va Binding to Membranes Containing Acidic Phospholipids," <u>J. Biol. Chem.</u> , 269(3):1905-1910 (1994)
18	Saenko et al., "A Mechanism for Inhibition of Factor VIII Binding to Phospholipid by von Willebrand Factor," <u>J. Biol. Chem.</u> , 270(23):13826-13833 (1995)
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DATE CONSIDERED	
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DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRAN- SLATION IF APPRO- PRIATE

## OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)

19	Scandella et al., "In Hemophilia A and Autoantibody Inhibitor Patients: The Factor VIII A2 Domain and Light Chain Are Most Immunogenic," <u>Thrombosis Res.</u> , 101:377-385 (2001)
20	Woodle et al., "Versatility in Lipid Compositions Showing Prolonged Circulation with Sterically Stabilized Liposomes," <u>Biochimica et Biophysica Acta</u> , 1105:193-200 (1992)
21	Klibanov et al., "Amphipathic Polyethyleneglycols Effectively Prolong the Circulation Time of Liposomes," <u>FEBS Letters</u> , 268:235-237 (1990)
22	Papahadjopoulos et al., "Sterically Stabilized Liposomes: Improvements in Pharmacokinetics and Antitumor Therapeutic Efficacy," <u>Proc. Natl. Acad. Sci. USA</u> , 88:11460-11464 (1991)
23	Lasic et al., "Sterically Stabilized Liposomes: A Hypothesis on the Molecular Origin of the Extended Circulation Times," <u>Biochimica et Biophysica Acta</u> , 1070:187-192 (1991)
24	Pan et al., "Proposed Structure of the A Domains of Factor VIII by Homology Modelling," <u>Nature Structural Biol.</u> , 2(9):740-744 (1995)
25	Ptitsyn et al., "Evidence For a Molten Globule State as a General Intermediate In Protein Folding," <u>FEBS. Letters</u> , 262(1): 20-24
26	Lakowicz, <u>Principles of Fluorescence Spectroscopy, Second Edition</u> , New York, New York:Plenum Publishers, pp. 51-54 (1999)
27	Kirby et al., "Preparation of Liposomes Containing Factor VIII for Oral Treatment of Haemophilia," <u>J. Microencapsul.</u> , 1:33-45 (1984)
28	Kirby et al., "Incorporation of Factor VIII Into Liposomes," <u>Liposome Technology</u> , Vol. II, Boca Raton, FL: CRC Press, Inc. pp. 69-81 (1984)
29	Hemker et al., "Oral Treatment of Haemophilia A by Gastrointestinal Absorption of Factor VIII Entrapped in Liposomes," <u>The Lancet</u> , 1:70-71 (1980)

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